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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,039	07/31/2003	Szu-Min Lin	JJM-346CIP1	9647

26285 7590 01/26/2009

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EXAMINER	
JOYNER, KEVIN	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
01/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,039	LIN ET AL.	
	Examiner	Art Unit	
	KEVIN C. JOYNER	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *15,17,18 and 20* is/are allowed.

6)☒ Claim(s) *1,2,4-14 and 19* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/31/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Claim Objections

1. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4-14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Addy et al. (U.S. Patent No. 5,961,921) in view of Ferrel (U.S. Patent No. 5,653,045).

Concerning claims 1, 9 and 10, Addy discloses a method for cleaning and sterilizing a medical device comprising:

Placing the device into a container;

Treating the device in the container with a liquid substance comprising hydrogen peroxide (concerning claims 6, 7, 13, 14 and 16; column 7, lines 15-30), wherein a predetermined amount of the liquid substance is retained in the container (column 7, lines 1-10; column 7, lines 55-68; column 23, lines 12-26);

Vaporizing the liquid substance in the container to create a sterilant vapor; and

Contacting the device with the vapor to effect sterilization of the device (abstract). More specifically, Addy discloses that the liquid substance contacts the device and is vaporized to complete sterilization of the device, wherein contacting the device with said substance includes physical placement and condensation or aerosol spray. The physical placement is defined by Addy as placing a reservoir containing the substance in contact with the device (column 7, lines 1-10). As such the substance is retained in the reservoir. Furthermore, applying a spray of the substance to the device would require a certain amount of time in order to contact the entire device. During this process, at least a portion of the substance which has already been sprayed on the device is retained, as retain is defined as holding in place or continuing to use. Addy does not appear to disclose cleaning the device with a cleaning solution or rinsing the device with a rinse solution comprising hydrogen peroxide (concerning claims 4, 5, 11, 12, 17 and 18). Ferrel discloses a method for cleaning and decontaminating (column 5, lines 40-45) wafer devices or medical devices (although the process is described for a silicon wafer, it is noted column 11, lines 40-43 that the process is suitable for medical devices), comprising cleaning the device with a cleaning solution and rinsing the device with a rinsing solution comprising hydrogen peroxide. The cleaning process is provided in order to remove organic contamination while the rinsing process is provided to rinse said cleaning solution and remove non-metallic particles (column 3, lines 45-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to clean the device in the container of Addy with a cleaning solution and rinse

the device in the container with a rinsing solution to remove organic contamination and non-metallic particles and subsequently rinse the cleaning solution from said device as exemplified by Ferrell. Concerning claim 8, Addy continues to disclose a method further comprising introducing the liquid substance as a mist (column 3, line 10 states that the introduction of the liquid substance can happen in a plurality of ways including aerosol spray. As broadly interpreted, an aerosol spray produces a mist.). With regard to claim 19, Addy continues to disclose that at least a portion of the liquid substance comprises water (column 20, lines 25-45).

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Addy et al. (U.S. Patent No. 5,961,921) in view of Ferrel (U.S. Patent No. 5,653,045) as applied to claim 1 above, and further in view of Langford (U.S. Patent No. 5,711,921).

Addy in view of Ferrel is relied upon as set forth in reference to claim 1. Addy in view of Ferrel does not appear to disclose a method according to claim 1 further comprising storing the device in the container in sterile form. Langford discloses a method with an improved apparatus, which can be used, for cleaning and/or sterilizing devices. The patent further discloses a method comprising storing the device in a container in sterile from (as disclosed in column 6, lines 32-37; the device is an endoscope). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method as shown by Addy in view of Ferrel to include the step of storing the device in the container in sterile form as shown by Langford. This eliminates the need for transporting the sterilized device to a storing compartment thus reducing the chances for the device to become contaminated again.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 4-14 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 11/024,118. Although the conflicting claims are not identical, they are not patentably distinct from each other because all of the limitations in the claims of the instant application are met with respect to claims 1-19 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

7. Applicant's arguments filed on October 22, 2008 with respect to claim 1 has been fully considered but are not persuasive.

a) The Applicant argues that the Examiner has failed to clearly articulate the reasoning in support of the asserted conclusion of obviousness in view of the combined teaching of Addy and Ferrel and that there is no reason why one of ordinary skill in the art would arrive at the method for cleaning and sterilizing a medical device as recited in claim 1.

As set forth in the previous Office Action and reiterated above, Addy, among other things, discloses a method of sterilizing a medical device by vaporizing a liquid

substance of hydrogen peroxide to effect sterilization. Ferrel discloses a method of cleaning, rinsing and sterilizing medical devices utilizing hydrogen peroxide. More specifically, as noted in column 5 lines 40-50, there is an emphasis in the process on cleaning, **purifying, or otherwise eliminating contamination**. This is a disclosure of sterilizing the devices. As such, the procedures are analogous wherein one of ordinary skill would utilize the cleaning and rinsing steps of Ferrel in the method of Addy in order to initially remove organic contamination from the devices and subsequently rinse the cleaning solution from said device (as exemplified by Ferrel; column 3, lines 45-55), before the decontamination step of Addy as set forth above. As such, a clear reasoning has been presented with motivation to combine the references, wherein the combination is analogous and meets the limitations of claim 1.

b) The Applicant also argues that one of ordinary skill would not be inclined to combine the teaching of Addy and Ferrel to arrive at the claimed invention because the cleaning process of Ferrel included a final hydrochloric acid rinse that results in hydrochloric acid remaining in the chamber following cleaning and rinsing of the medical device. One of ordinary skill in the art would understand that vaporizing the remaining hydrochloric acid in the container could create a potentially hazardous situation which would destroy the principle function of Addy, which is to provide a non-hazardous method of sterilization.

Column 3 lines 55-65, column 4 lines 25-40 and column 12 lines 1-2, disclose that the hydrochloric rinse is followed by the application of deionized water to the

device, which rinses the hydrochloric acid from the device. As such, there would be no hydrochloric acid in the chamber following the rinsing procedures. Therefore, a non-hazardous method of sterilization is provided by the combination. Furthermore, medical devices are not limited to devices comprising metals and plastics. Numerous medical devices are comprised of glass, wherein one of ordinary skill would utilize the method set forth above on such devices. Consequently, no such hazardous situations would exist.

c) The Applicant continues to argue that the cleaning and rinse solutions of Ferrel would leave remnants of hydrochloric acid that would become vaporized. One of ordinary skill in the art would recognize that vaporizing hydrochloric acid in the presence of potentially incompatible materials used in medical devices would create a potentially hazardous condition.

This argument is persuasive. As set forth above, the cleaning and rinsing steps of Ferrel include the application of deionized water to the device, which would create a process that does not vaporize hydrochloric acid. However, with regard to claims 3 and 15, there is no disclosure or suggestion of retaining the rinse solution of Ferrel and vaporizing the rinse solution to effect sterilization of the device. As such, the argument is persuasive with respect to claims 3 and 15.

Allowable Subject Matter

8. Claims 15, 17, 18 and 19 are allowed.

9. The following is a statement of reasons for the indication of allowable subject matter:

The closest prior art of record does not teach, suggest or disclose a method for sterilizing a medical device comprising cleaning the device with a cleaning solution, rinsing the device with a rinse solution, retaining a portion of a liquid substance comprising a portion of the rinse solution, and vaporizing the liquid substance to create a sterilant vapor and sterilize said device.

As set forth above, Addy discloses a method of sterilizing a medical device comprising contacting the device with a liquid substance and vaporizing the liquid substance in a container to create a sterilant vapor, wherein the vapor contacts the medical device to sterilize the device. Addy does not disclose cleaning the device, rinsing the device, and retaining a portion of a liquid substance comprising a portion of the rinse solution wherein the liquid substance is vaporized to effect sterilization of the device. Ferrel discloses a method of placing a device in a container, cleaning the device, rinsing the device and sterilizing the device. Ferrel does not disclose that the device is sterilized by vaporizing a liquid substance in a container to sterilize the device, wherein the liquid substance comprises a retained portion of the rinsing solution.

Therefore, the closest prior art of record does not teach, suggest or disclose a method for sterilizing a medical device comprising placing the device in a container, cleaning the device, rinsing the device, and vaporizing a liquid substance in a container to effect sterilization of the device, wherein the liquid substance comprises a retained portion of the rinse solution.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN C. JOYNER whose telephone number is (571)272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

KCJ